

**Appendix A: Defendants' Improperly-Submitted Extraneous Exhibits**

<b>Def. Ex. No.</b>	<b>Description</b>	<b>Document Type</b>	<b>Cited by Def. Br. at</b>	<b>Why the Submission Is Impermissible</b>
2.	B.F. McAdam, <i>et al.</i> , "Systemic Biosynthesis of Prostacyclin by Cyclooxygenase (COX)-2: The Human Pharmacology of a Selective Inhibitor of COX-2," PHARMACOLOGY, Vol. 96, at 272-77 (Jan. 1999).	Medical journal article	p. 6, n.3 p. 7 p. 52	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not properly submitted for purported truth on the market defense because Defendants mischaracterize Plaintiffs' claims</li> </ul>
3.	Jane A. Mitchell and Timothy D. Warner, "COX Isoforms in the Cardiovascular System: Understanding the Activities of Non-Steroidal Anti-inflammatory Drugs," NATURE REVIEWS, Vol. 5, at 75-85 (Jan. 2006).	Medical journal article	p. 6, n.3 p. 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
5.	Carlo Patrono, <i>et al.</i> , "Platelet-Active Drugs: The Relationship Among Dose, Effectiveness, and Side Effects," CHEST, Vol. 114, at 470S-488S (Nov. 1998).	Medical journal article	p. 7	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
6.	M. Michael Wolfe, <i>et al.</i> , "Gastrointestinal Toxicity of Nonsteroidal Anti-inflammatory Drugs," NEW ENGLAND JOURNAL OF MEDICINE, Vol. 340:24, at 1888-99 (June 17, 1999).	Medical journal article	p. 7	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
7.	Marcelo Muscará, <i>et al.</i> , "Selective Cyclo-oxygenase-2 Inhibition with Celecoxib Elevates Blood Pressure and Promotes Leukocyte Adherence," BRITISH JOURNAL OF PHARMACOLOGY, Vol. 129, at 1423-1430 (April 2000).	Medical journal article	p. 7	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>

Def. Ex. No.	Description	Document Type	Cited by Def. Br. at	Why the Submission Is Impermissible
8.	Stacey Burling, "Penn Study Hints at Risks with Cox-2 Painkillers," <i>The Philadelphia Inquirer</i> , at D12 (Feb. 1, 1999).	Press article	p. 7, n.5 p. 52	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not properly submitted for purported truth on the market defense because Defendants mischaracterize Plaintiffs' claims</li> </ul>
9.	Ric Day, <i>et al.</i> , "A Randomized Trial of the Efficacy and Tolerability of the Cox-2 Inhibitor Rofecoxib vs Ibuprofen in Patients with Osteoarthritis," ARCHIVES OF INTERNAL MEDICINE, Vol. 160 (June 26, 2000).	Medical journal article	p. 7	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
10.	Grant W. Cannon, <i>et al.</i> , "Rofecoxib, A Specific Inhibitor of Cyclooxygenase 2, with Clinical Efficacy Comparable with that of Diclofenac Sodium: Results of a One-Year, Randomized, Clinical Trial in Patients with Osteoarthritis of the Knee and Hip," ARTHRITIS & RHEUMATISM, Vol. 43:5, at 978-87 (May 2000).	Medical journal article	p. 7	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
11.	Leslie J. Crofford, "Clinical Experience with Specific COX-2 Inhibitors in Arthritis," CURRENT PHARMACEUTICAL DESIGN, Vol. 6, at 1725-36 (2000).	Medical journal article	p. 7	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
13.	FDA Medical Officer Review, "VIOXX (Rofecoxib) NDA 21-042 (capsules) and NDA 21-052) (oral solution)" (signed May 20 and 26, 1999).	FDA document	pp. 7-8 p. 9	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability during the Class Period</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>

<b>Def. Ex. No.</b>	<b>Description</b>	<b>Document Type</b>	<b>Cited by Def. Br. at</b>	<b>Why the Submission Is Impermissible</b>
14.	FDA Memorandum from Juan Carlos Pelayo of the FDA (dated April 30, 1999).	FDA document	pp. 7-8 p. 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
15.	FDA Medical Officer Review, “NDA 21-042 and NDA 21-052 (Rofecoxib tablets and oral solution)” (dated Nov. 28, 2001).	FDA document	p. 8 p. 10, n.7 p. 42 p. 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
17.	FDA Memorandum, “Cardiovascular data in Alzheimer’s studies” (dated March 12, 2002).	FDA document	p. 8	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
18. and 19.	Letter from Merck’s Ned S. Braunstein to Dr. Lee Simon of the FDA dated July 22, 2002 (Def. Ex. 18), attaching Merck’s Clinical Study Report for Study 091, dated June 4, 2002 (Def. Ex. 19).	Merck documents	p. 8 p. 48 p. 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability. Exhibit 18 states Merck “consider[s] the information included in this submission to be a confidential matter, and request[s] that the [FDA] not make its content . . . public without first obtaining the written permission” of Merck</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>

Def. Ex. No.	Description	Document Type	Cited by Def. Br. at	Why the Submission Is Impermissible
20. and 21.	Letter from Merck's Diane Louie to Dr. Brian E. Harvey of the FDA dated December 17, 2003 (Def. Ex. 20), attaching Merck's Clinical Study Report for Study 078, dated November 24, 2003 (Def. Ex. 21).	Merck documents	pp. 8-9 48 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability. Exhibit 20 states Merck "consider[s] the information included in this submission to be a confidential matter, and request[s] that the [FDA] not make its content . . . public without first obtaining the written permission" of Merck</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
23.	Merck Press Release, "Merck Submits New Drug Application for Vioxx, an Investigational Cox-2 Specific Inhibitor" (Nov. 23, 1998).	Press release	p. 9	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
26.	FDA Memorandum, "Consultation NDA 21-042, S-007; Review of cardiovascular safety database" (Feb. 1, 2001).	FDA document	p. 10	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
27.	Claire Bombardier, <i>et al.</i> , "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis," NEW ENGLAND JOURNAL OF MEDICINE Vol. 343:21 (Nov. 23, 2000).	Medical journal article	p. 21 p. 22	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
29.	FDA Medical Officer Review, "VIOXX (Rofecoxib); NDA 21-042 (capsules) and NDA 21-052 (oral solution) S 007 (Gastrointestinal Safety) (Mar. 30, 2001)	FDA document	p. 21	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>

Def. Ex. No.	Description	Document Type	Cited by Def. Br. at	Why the Submission Is Impermissible
32.	Garrett FitzGerald and Carlo Patrono, "The Coxibs, Selective Inhibitors of Cyclooxygenase-2," NEW ENGLAND JOURNAL OF MEDICINE, Vol. 345:6 (August 9, 2001).	Medical journal article	p. 11	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
33.	Carlo Patrono, "Efficacy and safety of aspirin in the long-term management of atherosclerosis," HAEMATOLOGICA Vol. 86, at 19-21 (Nov. 2001).	Medical journal article	p. 11	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
34.	Garrett FitzGerald, <i>et al.</i> , "COX-2 inhibitors and the cardiovascular system," CLINICAL AND EXPERIMENTAL RHEUMATOLOGY, Vol. 19, at S31-S36 (2001).	Medical journal article	p. 11	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
36.	Marvin A. Konstam, <i>et al.</i> , "Cardiovascular Thrombotic Events in Controlled, Clinical Trials of Rofecoxib," CIRCULATION, Vol. 104, at r15-r23 (Oct. 15, 2001).	Medical journal article	p. 49	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
38.	"Scientists: Arthritis Painkiller Vioxx Causes Fewer Ulcers than Naproxen," <i>Associated Press</i> (Feb. 8, 2001).	Press article	p. 12	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
39.	Carl Seiden, "Merck's VIGOR Trial Confirms Vioxx's G.I. Safety (with a Slight Cardiovascular Wrinkle)," JP Morgan Securities (March 28, 2000).	Analyst report	p. 12 p. 23, n.19	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>

Def. Ex. No.	Description	Document Type	Cited by Def. Br. at	Why the Submission Is Impermissible
40.	Carl Seiden, “Expect FDA Cox-2 Label Changes to Benefit Both Celebrex (PHA/PFE) and Vioxx (MRK),” JP Morgan Securities (Feb. 2, 2001).	Analyst report	p. 12 p. 53	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not properly submitted for purported truth on the market defense because Defendants mischaracterize Plaintiffs’ claims</li> </ul>
47.	Fadia T. Shaya, <i>et al.</i> , “Selective Cyclooxygenase-2 Inhibition and Cardiovascular Effects,” Archives of Internal Medicine, Vol. 165, at 181-86 (Jan. 24, 2005).	Medical journal article	pp. 15-16	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
48.	Elham Rahme, <i>et al.</i> , “Association between Rofecoxib, Diclofenac/Ibuprofen and Hospitalization for Acute Myocardial Infarction,” PHARMACOEPIDEMIOLOGY AND DRUG SAFETY, Vol. 13, at S235 (July 2004).	Medical journal article	pp. 15-16	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
49.	Stephen E. Kimmel, <i>et al.</i> , “The Effects of Nonselective Non-Aspirin Non-Steroidal Anti-Inflammatory Medications on the Risk of Nonfatal Myocardial Infarction and their Interaction with Aspirin,” JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY, Vol. 43:6 (March 17, 2004).	Medical journal article	p. 16 p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>

Def. Ex. No.	Description	Document Type	Cited by Def. Br. at	Why the Submission Is Impermissible
50.	Marta L. Capone, “Clinical Pharmacology of Platelet, Monocyte, and Vascular Cyclooxygenase Inhibition by naproxen and Low-Dose Aspirin in Healthy Subjects,” CIRCULATION, Vol. 109, at 1468-71 (March 30, 2004).	Medical journal article	p. 16 p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
51.	Douglas J. Watson, <i>et al.</i> , “Lower Risk of Thromboembolic Cardiovascular Events with naproxen Among Patients with Rheumatoid Arthritis,” ARCHIVES OF INTERNAL MEDICINE, Vol. 162, at 1105-1110 (May 27, 2002).	Medical journal article	p. 16 p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
52.	Elham Rahme, <i>et al.</i> , “Association between Naproxen Use and Protection Against Acute Myocardial Infarction,” ARCHIVES OF INTERNAL MEDICINE, Vol. 162, at 1111-1115 (May 27, 2002).	Medical journal article	p. 16 p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
53.	Daniel H. Solomon, <i>et al.</i> , “Nonsteroidal Anti-inflammatory Drug use and Acute Myocardial Infarction,” ARCHIVES OF INTERNAL MEDICINE, Vol. 162, at 1099-1104 (May 27, 2002).	Medical journal article	p. 16 p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
55.	FDA Press Release, “FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product” (Sept. 30, 2004).	Press release	p. 16	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>



Def. Ex. No.	Description	Document Type	Cited by Def. Br. at	Why the Submission Is Impermissible
56.	Committee Hearing Transcript, “U.S. Senator Charles E. Grassley (R-IA) Holds Hearing on FDA, Merck and Vioxx: Putting Patient Safety First, Part 1” (Nov. 18, 2004)	Transcript	p. 16 p. 37	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
57.	FDA Interim Review: Review of NDA 21042/s030 (Update of Cardiovascular Thrombotic Events in Alzheimer’s studies 078 and 091) (Dec. 18, 2004).	FDA document	p. 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
58.	FDA Memorandum from John J. Jenkins to file, “Analysis and Recommendations for Agency Action Regarding Non-steroidal Anti-inflammatory Drugs and Cardiovascular Risk” (April 6, 2005).	FDA document	p. 57	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
63.	FDA Medical Officer’s Consult Review, “Effect of Vioxx on Platelet Function” (April 6, 1999).	FDA document	p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
64.	Anne van Hecken, <i>et al.</i> , “Comparative Inhibitory Activity of Rofecoxib, Meloxicam, Diclofenac, Ibuprofen, and Naproxen on COX-2 versus COX-1 in Healthy Volunteers,” JOURNAL OF CLINICAL PHARMACOLOGY, Vol. 40, at 1109-1120 (Oct. 2000).	Medical journal article	p. 23	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
74.	Merck presentation to the FDA Arthritis Advisory Committee concerning VIGOR (Feb. 8, 2001)	Merck document	p. 42 p. 43	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>



<b>Def. Ex. No.</b>	<b>Description</b>	<b>Document Type</b>	<b>Cited by Def. Br. at</b>	<b>Why the Submission Is Impermissible</b>
76.	Merck Memorandum from T. Musliner, “Anticipated consequences of NSAID antiplatelet effects on cardiovascular event and effects of excluding low-dose aspirin use in the Cox-2 GI Outcomes Megatrial” (Nov. 21, 1996).	Internal Merck document	p. 43	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>
77.	Draft Protocol for Merck’s “MK-0966 GI Clinical Outcomes Study” (Feb. 25, 1997).	Internal Merck document	p. 44	<ul style="list-style-type: none"> <li>• Not cited in or integral to Complaint</li> <li>• No showing of public availability</li> <li>• Submitted for the truth of the matter asserted</li> <li>• Not submitted for purported truth on the market defense</li> </ul>